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10/771,242	04/13/2004	Daniella I. Zheleva	CCI-014CP2	9212

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,242	ZHELEVA ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-54,57-66 and 69-73* is/are pending in the application.

4a) Of the above claim(s) *51-54,57-66 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-50,69,71-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendments and arguments filed 9/18/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

In the reply dated 9/18/08 claims 49-51 were amended. Claims 1-48,55-56,67-68 have been cancelled.

As noted previously, applicant has elected species of SEQ ID NO:295, H-Arg-Arg-Leu-Asn-pFPhe-NH2. The elected species was found to be obvious based on the prior art (see 103 rejection below). As such, SEQ ID NO:295 is not free of the prior art.

Claims 51-54,57-66,70 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

It is noted that claims 49-50,69 are indefinite (see 112 2nd below). Claims 49-50,69 have been interpreted as reading on the elected species.

Claims 49-50,69,71-73 are under consideration.

Priority

Applicants arguments are found convincing with respect to the instant claims having a priority of at least 5/19/03. Since the instant application also claims priority (as a CIP) to 09/726,470 (11/29/00) the priority with respect to 09/726,470 is discussed herein.

This application is properly designated a continuation-in-part (CIP) of 09/726,470. In the instant case, the pending claims are not supported by the parent application 09/726,470.

Pending claims 49-50,69 are drawn to variants of SEQ ID NO:293 and pending claims 71-73 are drawn to SEQ ID NO: 295-376.

The specification of 09/726,470 is void of any literal support for any of SEQ ID NO:293, SEQ ID NO: 295-376.

Determination of support for new claims is highlighted in MPEP 2163. The MPEP states, "[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." Although the current application is a new application (no new claims) the analysis in determining support in the parent applications is similar.

The specification of 09/726,470 is void of any express, implicit, or inherent support for any of SEQ ID NO:293, SEQ ID NO: 295-376. There is nothing in the disclosure of 09/726,470 to lead one to any of SEQ ID NO:293, SEQ ID NO: 295-376. Hence it can not be said that 09/726,470 provides support for the instant claims.

As such, for purposes of searching for prior art, 5/19/03 is used as the relevant priority date for the instant claims.

Response to Arguments Priority

As stated above, Applicants arguments are found convincing with respect to the instant claims having a priority of at least 5/19/03. However, since applicant has provided no arguments as to why the instant claims should have a priority date prior to 5/19/03, as discussed above 5/19/03 is used as the relevant priority date for the instant claims.

Claim Rejections - 35 USC § 112

Claims 49-50,69 were previously rejected under 112 2nd paragraph. Since the claims have been amended a rejection with respect to the instant claims appears below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-50,69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 49-50 (and dependent claim 69) are drawn to peptides consisting of a variant of formula V. It is noted that claim 50 recites '…a variant of formula V….or a variant thereof…'. The metes and bounds of the claims are unclear. First, it is unclear if the claims are drawn to variants where the variants must have the structural elements recited in the claim or if the claims are drawn to variants of formula V which are not limited to any elements of formula V or the recited structural features. As such, there is more than one reasonable interpretation of the instant claims. In other words, there is a distinction between i) a peptide that consists of X, ii) a peptide that consists of a variant of X and iii) a peptide that consists of a variant of X wherein the variant consists of certain elements. In particular, a peptide that consists of a variant of X is much broader than a peptide that consists of X. It is noted that the specification (page 22 first complete paragraph) recites a definition for variant. The definition states that variants include the peptides of SEQ ID NO:1,2, and 3. However, the instant claims are not necessarily drawn to SEQ ID NO:1,2, or 3. Thus it is unclear if the recited definition is applicable to the instant claims. As

such, the scope of 'variant' is unclear. Further, the definition states that variants include 'dual peptides'. However, it is unclear what is meant by dual peptide. The term 'dual peptide' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

As noted previously, SEQ ID NO:293 contains a Phe at the X9 position based on the specification and sequence listing. Although applicant previously indicated that a revised sequence listing would be filed (1/14/08 page 12 2nd complete paragraph) no such listing has been provided. Further, it is noted that dependent claim 69 states that the N-terminus can be acylated. However, base claims 49-50 use 'consisting' language which is closed language and is not open to other elements (see MPEP section 2111.03). As such, it is unclear if the genus of claims 49-50 are drawn to variants of formula V such that the variant can include acylation or other modifications, or if claim 69 is an improper dependent claim.

It is noted that applicants elected species includes a c-terminal amide. However, X9 of claim 49 does not recite amidated groups at such position. As such, it is unclear if the genus of claims 49-50 are drawn to variants of formula V such that the variant can include amidation or other modifications, or if the elected species does not read on claims 49-50.

This rejection is a new rejection based on applicants amendments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-50,69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to peptide variants.

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

Although unclear (see 112 2nd) for purposes of examination claims 49-50,69 have been interpreted such that the claims read on variants of the recited formulas where the variants are given the broadest reasonable interpretation (see MPEP section 2111). Although the definition of variant is unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that any number of deletions, additions, and substitutions are permissible. As such, the term variant includes at least one of: deletion, addition or substitution (compare page 22 first paragraph) for example. It is noted that 'at least one' could many any number such as 200. In considering the size of the genus, if R and X6-X9 (of claims 49-50,69) are substituted with any of the 20 naturally occurring amino acids and 5 additional residues are added which could be any of the 20 naturally occurring amino acids, there are at least 20^{10} (i.e. 10240000000000) different peptides within the genus. Further, the genus includes non-natural amino acids, chemical derivatives, and cyclic peptides. Hence, the genus is large and there is substantial variability in the genus.

The specification and sequence listing does recite numerous sequences and recites an overview of variants (page 22). However, such disclosure is not representative of the instant genus of peptides. One of skill in the art would not recognize that applicant was in possession of the claimed genus. Since there are a substantial variety of polypeptides possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

The instant peptides are described as inhibitors (abstract). The claims are drawn to variants. Although the definition of variant is unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that any number of deletions, additions, and substitutions are permissible. The definition for variant (page 22 first paragraphs) states that the variants 'retain the activity of the parent peptide'. However, there are no specific common attributes or characteristics that identify the activity of the parent peptide. The instant claims are not limited to a common core structure. Although the instant specification does provide examples and data for numerous peptides such data is not sufficient for one of skill in the art to recognize which variants (from the over at least 10240000000000 see above) would have the activity of the parent peptide. There is no specific teaching in the specification regarding what part of the structure can be varied while retaining the activity. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that there is a lack of the knowledge in the art regarding which amino acids can vary (via substitution, deletion, or addition) to maintain the function and thus that the applicant was not in possession of the claimed genus.

(5) Method of making the claimed invention:

The specification (specifically page 43) describes the synthesis of peptides. However, such guidance does not lead one to recognize which variants would have the activity of the parent peptide.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 49-

50,69 is/are broad and generic, with respect to all possible variants encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the polypeptides beyond those polypeptides specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of polypeptides identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of polypeptides embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

This rejection is necessitated by applicants amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49-50,69 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheleva et al. (WO 01/40142 as cited previously).

Zheleva teach p21 derived inhibition peptides (abstract). Zheleva specifically teach the peptide (page 74, 27th peptide listed) H-Ala-Ala-Lys-Arg-Arg-Leu-Asn-pFPhe-NH2 which corresponds to residues 152-159 (page 7 lines 7-10). Zhelava teach acylation reactions in preparing the peptide (page 62 lines 16-21) as recited in instant claim 69.

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation (see MPEP section 2111). Since dependent claim 69 includes acylation and the elected species includes amidation which are not elements of X6-X9 of claims 49-50, the claims have been interpreted such that the claims are drawn to variants of formula V which are not limited to any elements of formula V or the recited structural features. In other words, a variant of claims 49-50 can include variations of X6-X9 as recited in the claims. Although the definition of variant is unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that any number of deletions, additions, and substitutions are permissible.

In the instant case, Zheleva specifically teach the peptide (page 74, 27th peptide listed) H-Ala-Ala-Lys-Arg-Arg-Leu-Asn-pFPhe-NH2. In relation to the instant claims X6 is Arg, X7 is Leu, X8 is Asn, X9 is parafluorophenylalanine (pFPhe). The definition of variant (page 22 line 3-5) states that there can be at least one addition. In the instant case, Ala-Ala-Lys is the addition. Thus the peptide is a variant, meeting the limitations of claim 49. With respect to claim 50, R is unchanged as recited in the wherein clause (see claim 50(a)). Thus the peptide of Zheleva meet

the limitations of claim 50. Zhelava teach acylation reactions in preparing the peptide (page 62 lines 16-21) as recited in instant claim 69.

Response to Arguments 102

Applicants arguments regarding the 102 rejection via Fischer are found persuasive since, as discussed above, 5/19/03 is used as the relevant priority date for the instant claims. The above rejection via Zheleva is a new rejection necessitated by applicants amendment and no arguments have been set forth with respect to 102 rejections via Zheleva.

Claim Rejections - 35 USC § 103

Claims were previously rejected under 103 using the references cited below. Since the claims have been amended the rejection has been updated to relate to the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49-50,69,71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheleva et al. (WO 01/40142 as cited previously) and Mutoh et al. (Cancer research 1999 v59 3480-3488 as cited previously).

Zheleva teach p21 derived inhibition peptides (abstract). Zheleva specifically teach the peptide (page 74, 27th peptide listed) H-Ala-Ala-Lys-Arg-Arg-Leu-Asn-pFPhe-NH2 which corresponds to residues 152-159 (page 7 lines 7-10). Zheleva teach that the pFPhe derivative is desirable (page 80 last paragraph) as it results in more complementary interactions. Zheleva teach that residues may be deleted from the N-terminal end (claim 1; page 4 lines 24-26), for example in one embodiment residues 155-159 are the peptide of interest (page 6 lines 4-12). Zhelava teach acylation reactions in preparing the peptide (page 62 lines 16-21).

Zheleva does not expressly teach the elected peptide H-Arg-Arg-Leu-Asn-pFPhe-NH2.

Mutoh et al. teach p21 derived inhibitory peptides (abstract). Mutoh specifically teach that residues 155-159 are important for retention of the inhibitory activity (page 3485 lines 13-15).

Since Zheleva specifically teach the peptide (page 74, 27th peptide listed) H-Ala-Ala-Lys-Arg-Arg-Leu-Asn-pFPhe-NH2 which corresponds to residues 152-159 of p21 (page 7 lines 7-10) and further teach that residues may be deleted from the N-terminal end (claim 1; page 4 lines 24-26; page 6 lines 4-12) one would be motivated to delete residues from the N-terminal end. Since

Mutoh specifically teach that residues 155-159 of p21 are important for retention of the inhibitory activity (page 3485 lines 13-15) one would be motivated to delete Ala-Ala-Lys from the peptide taught by Zheleva to arrive at H-Arg-Arg-Leu-Asn-pFPhe-NH2 which is the elected species and meets the limitations of claims 49-50,71-73 of the instant invention. Since Zheleva teach acylation reactions in preparing the peptide (page 62 lines 16-21) the limitations of claim 69 are met. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation (see MPEP section 2111). Since dependent claim 69 includes acylation and the elected species includes amidation which are not elements of X6-X9 of claims 49-50, the claims have been interpreted such that the claims are drawn to variants of formula V which are not limited to any elements of formula V or the recited structural features. In other words, a variant of claims 49-50 can include variations of X6-X9 as recited in the claims. Although the definition of variant is unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that any number of deletions, additions, and substitutions are permissible. The instant 103 rejection is on the elected species which is interpreted as reading on claims 49-50,69,71-73.

Response to Arguments 103

Since the claims have been amended the rejection has been updated to correspond to the instant claims. The arguments will be considered with respect to the instant rejection.

Applicants argue that the rejection is based on impermissible hindsight. Applicants argue that a peptide has to be picked from a list and that three residues have to be deleted. Applicants argue that Mutoh teach away since Mutoh teach that modifications have been shown to disrupt structure.

Applicant's arguments filed 9/18/08 have been fully considered but they are not persuasive.

Although applicants argue that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Although applicants argue that a peptide has to be picked from a list and that three residues have to be deleted, alternative embodiments do not constitute a teaching away. Although Zheleva teach numerous peptides, alternative embodiments do not constitute a teaching away (see MPEP section 2123 II). In the instant case, Zheleva teach residues 155-159 as the peptide of interest (page 6 lines 4-12). Mutoh also teach that residues 155-159 are important for retention of the inhibitory activity (page 3485 lines 13-15). Further, "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton."KSR, 550 U.S. at ___, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."Id. Office personnel may also take into account

"the inferences and creative steps that a person of ordinary skill in the art would employ."Id. at ___, 82 USPQ2d at 1396.

Although Applicants argue that Mutoh teach away since Mutoh teach that modifications have been shown to disrupt structure, it is noted that the instant rejection is a multiple reference 103 rejection. As such, a single reference does not teach the elected species, for example. In the instant case, Zheleva teach residues 155-159 as the peptide of interest (page 6 lines 4-12). Mutoh also teach that residues 155-159 are important for retention of the inhibitory activity (page 3485 lines 13-15). Zheleva teach that the pFPhe derivative is desirable (page 80 last paragraph) as it results in more complementary interactions. As such, one would recognize that the pFPhe modification is acceptable. Zheleva teach the peptides as p21 derived inhibition peptides (abstract). One would not take the disclosure of Mutoh to mean that any and all modifications would destroy all functionality. In the instant case, Zheleva teach the peptides as p21 derived inhibition peptides (abstract) and specifically teach the pFPhe derivative as desirable (page 80 last paragraph).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

This rejection appeared in the previous office action.

Claims 71-73 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 20,21, 22 of copending Application No. 11/407,880. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Response to Arguments statutory DP

Applicants argue that the prosecution of the present and copending application may render such rejection moot.

Applicant's arguments filed 9/18/08 have been fully considered but they are not persuasive.

Although Applicants argue that the prosecution of the present and copending application may render such rejection moot, the rejection remains of record. Applicant has not overcome the rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims were rejected previously under nonstatutory obviousness-type double patenting. Since the claims have been amended, the rejection has been updated.

Claims 49-50,69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16,17,18,20-23 of copending Application No. 11/407,880. Although the conflicting claims are not identical, they are not patentably distinct from each other. For example, the 2nd peptide of claim 20 of 11/407,880 reads on claims 49-50 of the instant invention. Claim 23 of 11/407,880 reads on claim 69 of the instant invention.

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation (see MPEP section 2111). Since dependent claim 69 includes acylation and the elected species includes amidation which are not elements of X6-X9 of claims 49-50, the claims have been interpreted such that the claims are drawn to variants of formula V which are not limited to any elements of formula V or the recited structural features. In other words, a variant of claims 49-50 can include variations of X6-X9 as recited in the claims. Although the definition of variant is unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that any number of deletions, additions, and substitutions are permissible.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments ODP

Applicants argue that the prosecution of the present and copending application may render such rejection moot.

Applicant's arguments filed 9/18/08 have been fully considered but they are not persuasive.

Although Applicants argue that the prosecution of the present and copending application may render such rejection moot, the rejection remains of record. Applicant has not overcome the rejection.

Conclusion

As discussed with the rejections above, as appropriate, applicants amendment to the claims such that the claims read on 'variants' necessitated new rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654